

COMMISSIONER FOR PATENT UNITED STATES PATENT AND TRADEMARK OFFIC WASHINGTON, D.C. 20231 www.usoto.go

MAR 1 7 2003

David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Dear Mr. Read:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 4,839,350. The application was filed on October 17, 2001, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

Karin Ferriter

Senior Legal Advisor

Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc:

B. Aaron Schulman

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ALEXANDRIA VA 22314-1437

RE: SPECTRACEFTM® Docket No. 03E-0036